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**BUREAU OF INDIAN STANDARDS**
**DRAFT FOR COMMENTS ONLY**



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*भारतीय मानक*

# स्किन ग्राफ्टिंग ब्लेड के लिए सामान्य आवश्यकताएं

**(*दूसरा संशोधन*)**

*Indian Standard*

# General Requirements for Skin grafting blade

**(*Second Revision*)**

**ICS 11.040.30**

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Surgical Instruments Sectional Committee, MHD 01

**Last date for comments**:
30 Oct 2022

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## NATIONAL FOREWORD

This Indian Standard is to be adopted by the Bureau of Indian Standards after the draft finalized by the Surgical Instruments Sectional Committee, MHD 01 and approved by Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1987 as 'IS 3759: 1987 'Specification for blades, skin grafting (First Revision)'. This first revision has been under taken to ensure the safety and biocompatibility of the material used in the manufacture of Surgical Instruments.

This Indian standard specifies the general requirement of skin grafting blades used in skin grafting knifes and dermatomes.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (Second Revision)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

## 1. SCOPE

**1.1.** This standard covers the general requirements of skin grafting blades used in skin grafting knifes and dermatomes.

## 2. REFERENCES

**2.1.** The following standard contains provision which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

**2.2.** The Indian Standards given below are necessary adjuncts to this standard.

| *Indian Standard* | *Title* |
|---|---|
| IS/ ISO 7153-1: 2016 | Surgical Instruments – Materials Part 1 Metals |
| IS 7531: 1990 | Surgical instruments - Corrosion resistance of stainless-steel surgical instruments - Methods of tests (First Revision) |
| IS 4905: 2015/ ISO 24153: 2009 | Random sampling and randomization procedures (First Revision) |

## 3. TERMINOLOGY

**3.1.** Skin Graft Blades are used in the surgical removal of a patch of healthy skin from one area of the patient's body, which is then transplanted to another.

## 4. CLASSIFICATION

**4.1.** The Blades shall be of different sizes as per the requirement of the purchaser.

## 5. MATERIAL COMPOSITION, PLATING AND PASSIVATION

**5.1.** The materials used in the manufacture of scalpels shall be as specified in IS/ ISO 7153-1: 2016

**5.2.** The Plating or the Surface finishing of the material shall be performed as per Plating or electropolishing is

**5.3.** The instruments shall be treated by a suitable passivation process, for example, by electropolishing or by treatment with 10 percent nitric acid solution for not less than 30 minutes at a temperature not less than 10°C and not exceeding 60°C. The instruments shall then be rinsed in water and dried in hot air.

## 6. SHAPE AND DIMENSIONAL REQUIREMENTS

**6.1.** The dimensions of scalpels and knives shall be in accordance with the requirements of individual specifications, unless otherwise specified by the purchaser.

## 7. MANUFACTURE

**7.1.** The blades shall be sharpened along the entire length of the cutting edge and shall include an angle of 161".

**7.2.** The blade shall be perfectly straight and the centres of the holes shall be equidistant from the cutting edge.

**7.3.** The cutting edge shall be perfectly straight, uniform throughout, surgically sharp and free from feathers, nicks, high spots and waviness.

**7.4.** The blades shall be highly polished and free from any blemishes. All edges, except the cutting edge, shall be rounded.

## 8. HARDENING AND MECHANICAL REQUIREMENTS

**8.1.** The Skin grafting blades shall be hardened and tempered to 800 to 850 HV.

## 9. FINISHING, WORKMANSHIP AND VISUAL REQUIREMENTS

**9.1.** The blade shall be highly polished and free from any blemishes. The test is carried out visually.

**9.2.** All edges except the cutting edge shall be rounded.

**9.3.** The cutting edge shall be surgically sharp and free from feathers, nicks, high spots, waviness or undulation.

**9.4.** The handle shall be finished smooth with a matt surface. It shall be free from burrs, sharp or rough edges, pits and other surface defects. The edge shall be chamfered.

## 10. TESTING AND PERFORMANCE REQUIREMENTS

**10.1.** The cutting edge of the blade shall be examined under a magnification of at least 60 X in two directions along and perpendicular to the plane of the cutting edge, and it shall not reveal any feather edge, nicks, high spots, waviness or undulation.

**10.2.** The blade shall be tested by cutting a piece of Chamois leather with moderate pressure at least five times. They shall cut easily and clearly along the entire length of the cutting edge. On completion of the test, the scalpel or knife shall show no sign of damage, when examined in accordance with 10.1.

**10.3.** The blade shall be corrosion resistance test provided in IS 7531: 1990.

## 11. MARKING

**11.1.** The blade shall be clearly and indelibly marked with the manufacturer's name or trade-mark. When the marking is done on the blade portion, it shall be done by electro etching.

**11.2.** The blade may also be marked with a Standard Mark.

**11.3.** The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the BIS Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

## 12. SAMPLING

**12.1.** The scale of sampling and criteria for conformity of the blade to requirements shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A.

## 13. PACKING

**13.1.** The blades shall be coated with a thin film of a solution containing corrosion inhibitors.

**13.2.** The blades shall be wrapped with sterilization wraps and sealed with a tape which is a biological indicator.

## ANNEX A

(Clause 12.1)

### A-1. LOT

**A-1.1.** In a consignment, all the blades of the same pattern and dimensions shall be grouped together to constitute a lot, not exceeding 50. Each lot shall be tested for the requirements of this specification.

### A-2. NUMBER OF INSTRUMENTS

**A-2.1.** Eight blades from the lot shall be selected at random by using random number tables (IS 4905: 2015/ ISO 24153: 2009 Random sampling and randomization procedures (First Revision)) and tested for the requirements of shape and dimensions (2). material (3), workmanship and finish (5). marking (71, and packing (8). Any blade failing to meet one or more of the above requirements shall be termed defective. No defectives shall be permitted in the sample if the lot is to be accepted under this clause.

**A-2.2.** The lot which has been found satisfactory as in A-2.1 shall be tested for other requirements. For this purpose, three blades shall be sampled and tested for feathers, nicks, etc (5.3 and 6.1) and performance requirements (6.2). One blade shall be tested for hardness (4). All samples shall pass the respective requirements if the lot is to be accepted under this clause.